



PATENT
674537-2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Coia *et al.*
Serial No. : 09/623,611
Filed : October 6, 2000
For : V-LIKE DOMAIN BINDING MOLECULES
Examiner : P. Gambel
Art Unit : 1644

745 Fifth Avenue, New York, NY 10151

EXPEDITED PROCEDURE
RESPONSE AFTER FINAL OFFICE ACTION
UNDER 37 C.F.R. 1.116

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DECLARATION UNDER 37 C.F.R. 1.132

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

We, Maria GALANIS, Peter HUDSON, Robert IRVING and Stewart NUTTALL, declare and state that:

1. We make this declaration in connection with U.S. application Serial No. 09/623,611, particularly with respect to the rejection under 35 U.S.C. §102(f) of claims 1-21, 28 and 34-41. The June 2, 2004 Office Action alleges that Nuttall *et al.* creates an ambiguity. Stated reasons for this purported ambiguity are that the disclosure of Nuttall overlaps with that of

the instant application, and that Inventors Coia and Galanis appear in the acknowledgements section of Nuttall, but are not authors.

2. We make this declaration to clarify the contributions of each inventor of the present application in view of the Nuttall *et al.* reference. The authors of Nuttall *et al.*, 1999 are Stewart Nuttall, Mat Rousch, Robert Irving, Simon Hufton, Hennie Hoogenboom and Peter Hudson.

Drs. Hudson and Irving are responsible for the initial broad concept of the invention, so their contribution was to all claims.

Dr. Coia was responsible for the claims related to the ribosomal display library (claims 30-32), work that was not reported in Nuttall *et al.* Since claims 30-32 have been cancelled due to the restriction requirement being maintained, Dr. Coia is removed as an inventor.

Dr. Galanis discovered the improved solubility of modified CTLA-4 using HPLC. This work was not specifically discussed in Nuttall *et al.* The concept of improved solubility is central to the invention, as it provided at least one incentive to develop modified monomeric VLDs. Furthermore, solubility characteristics are specifically recited in claim 38.

Dr. Nuttall performed the CDR substitutions, which contributed generally to independent claim 2 and specifically to dependent claims such as 4-6 and 41.

It will be appreciated that, in the scientific community, persons are or are not included as authors on scientific articles for reasons that do not involve issues of inventorship. Any work reported in Nuttall *et al.*, particularly work that may be common to the present application, was performed by or under the direction, supervision or control of the inventors on the present application.

3. In view of the foregoing, we request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(f).

4. All statements made herein, of our own knowledge, are true and all statements made on information and belief are believed to be true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 25/11/04



Maria GALANIS

Date: 22/11/04



Peter HUDSON

Date: 22/11/04



Robert IRVING

Date: 22/11/04



Stewart NUTTALL